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POSITIONER AND METHOD FOR A FEMORAL HIP IMPLANT

## BACKGROUND

[0001] Total hip arthroplasty is often used to restore function to a diseased or injured hip joint. Positions and directions relative to the hip joint may be described in terms of proximal being nearer the hip joint, distal being further from the hip joint, anterior being nearer the front of the body, posterior being nearer the back of the body, medial being nearer the centerline of the body, and lateral being further from the center line of the body. In total hip arthroplasty, the surfaces of the femur and pelvis are cut away and replaced with substitute implants. In a typical case, the implants include a hip stem component, a femoral head component, an acetabular component and bone cement.

[0002] The femoral bone is prepared by reaming the femoral canal down into the bone along an axis from a proximal position near the hip joint at the upper end of the femur toward a distal position nearer the knee joint at the lower end of the femur. The pelvis is prepared by reaming the acetabulum. The implants may be placed directly in contact with the prepared bone surfaces for bony fixation of the implant. Alternatively, bone cement may be introduced into the prepared canal and acetabulum so that it hardens around and locks the components in place.

[0003] The hip stem component includes a stem portion extending down into the intramedullary canal of the femur and a neck portion extending away from the femur to support the femoral head component. Some cemented hip stem designs rely on a tapered and highly polished exterior surface for use with cement to permit subsidence of the stem into the cement when the cement undergoes load induced deformation in use. By subsiding with the deforming cement, the implant maintains intimate contact with the cement.

[0004] Occasionally an undesirable upward force can occur that may withdraw a femoral component from the femoral canal. For example, if the femoral head dislocates from the acetabular component, a surgeon may attempt to reposition them by manipulating the patient's leg in a process known as a closed reduction. Sometimes, during this procedure, the femoral head can catch on the edge of the acetabular component causing the femoral implant to be lifted up such that surgical intervention is required.

[0005] Furthermore, for a cemented implant, positioning the femoral component in the correct orientation within the cement is important for proper biomechanical functioning and long term stability of the implants. Proper placement results in a uniform and strong cement mantle around the component. Proper placement further results in appropriate loading of the implants. Femoral components, especially collarless ones, are sometimes placed at the wrong angle in the mediolateral direction. The typical situation is a varus placement in which the angle between the neck and femoral axis is too shallow.

## SUMMARY

[0006] The present invention provides a positioner for controlling the position of a femoral hip implant within the intramedullary canal of a femur.

[0007] In one aspect of the invention, a positioner for implantation adjacent a femoral hip implant retains the femoral hip implant in the femoral canal. The positioner prevents the femoral hip implant from rising out of the femoral canal beyond a predetermined position. [0008] In another aspect of the invention, the positioner prevents the femoral hip implant from rising while permitting subsidence of the femoral hip implant down into the femoral canal.

[0009] In another aspect of the invention, a positioner includes an anchor portion securing the positioner adjacent the femoral canal and a retention portion extending from the anchor portion and over a portion of the implant such that it limits upward axial motion of the femoral hip implant.

[0010] In another aspect of the invention, a femoral hip system includes a femoral hip implant having a stem for insertion in a femoral canal and a retention member. The retention member has an anchor portion securing it in the femoral canal adjacent the femoral hip implant and a retention portion engageable with a portion of the femoral hip implant such that it blocks upward motion of the implant out of the canal while permitting downward motion of the implant into the canal.

[0011] In another aspect of the invention, a positioner includes an "L"-shaped body having a first leg positionable over a portion of the femoral hip implant relative to the canal axis. A second leg is simultaneously positionable adjacent the canal wall to maintain a predetermined spacing between the femoral hip implant and the canal wall.

[0012] In another aspect of the invention, a method includes providing a femoral hip implant configured to fit within a femoral canal; inserting cement into the femoral canal; inserting the femoral hip implant into the cement in the femoral canal; and inserting an implant retention member into the cement so that it becomes firmly attached to the cement upon hardening of the cement and permits the femoral hip implant to subside down into the cement but prevents it from rising up out of the cement beyond a predetermined position by engagement with the implant retention member.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Various embodiments of the present invention will be discussed with reference to the appended drawings. These drawings depict only illustrative embodiments of the invention and are not to be considered limiting of its scope.

[0014] FIG. 1 is a perspective view of an illustrative positioner according to the present invention;

[0015] FIG. 2 is a side section view taken along line 2-2 of FIG. 1 and further showing the positioner of claim 1 in combination with joint replacement implants; and [0016] FIG. 3 is a side section view taken along line 3-3 of FIG. 2.

## DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0017] A positioner is provided to control the position of a femoral hip implant within the intramedullary canal. The positioner may control the radial position of the femoral implant and/or the axial position by limiting movement of the femoral implant along the femoral axis. [0018] The positioner may prevent the femoral hip implant from rising out of the femoral canal beyond a predetermined position while permitting subsidence of the femoral hip implant into the femoral canal. The positioner may prevent any upward motion of the implant once it is inserted or it may allow a limited amount of upward motion. The positioner may allow unimpeded or a predetermined amount of subsidence into the femoral canal. The positioner may be anchored to the bone of the femoral canal and/or anchored in cement placed within the femoral canal. The positioner may be configured for use with a hip stem implant having a polished and tapered exterior surface. Such a surface permits the implant to move relative to the cement such that it subsides distally into the cement under load. For example, the positioner may be anchored in cement to limit upward motion of the implant relative to the cement while permitting the implant to subside into the cement in response to axial loading.

[0019] The positioner may include a portion overlying a portion of the implant in the direction of the longitudinal axis of the femoral canal so that the implant is prevented from rising by abutment against the overlying portion. The overlying portion may extend over the top of the implant and/or over an intermediate portion of the implant. The positioner may include multiple members with one or more members extending over a portion of the implant and one or more members extending into the bone and/or cement to anchor the positioner. The members may angle away from one another and/or form an "L", "U", saddle, and/or

other suitable shape. The individual members may have a round, rectangular, straight, tapered, and/or any other suitable cross sectional shape. The members may engage the femoral implant to retain the positioner on the femoral implant until they are inserted into the femoral canal. The members may fit loosely, fit tightly, be elastically biased against, or otherwise engage the implant. The members may be adjacent the implant or include projections that engage the implant and space the members from the implant to allow cement to be positioned between the implant and members. For example, the positioner may include a body with a plurality of legs extending downwardly and a projection extending inwardly from each leg that is biased to elastically grip the implant.

[0020] The positioner may control the radial position of the femoral hip implant relative to the wall of the femoral canal. The positioner may space the implant from the anterior, posterior, medial, and/or lateral aspects of the canal wall. The positioner may engage the implant initially when the implant and positioner are inserted into the femoral canal. The positioner may control the radial position of the implant during this initial period and then subsequently, under physiologic loads of patient use, permit the implant to move axially away from the positioner. For, example the positioner may maintain the radial position of the implant within the femoral canal while cement hardens around the implant and then, in use, allow the implant to subside into the implant under physiologic loads. The positioner may include a first portion engageable with the top of the implant and a second portion engageable with the wall of the femoral canal to space the implant a predetermined distance from the wall. For example, the first portion may include a boss extending downwardly to engage an opening in the top of the implant. The positioner may include members extending along the anterior, posterior, medial, and lateral sides of the implant to space the implant

from the wall of the femoral canal. The members may each include a tab engaging the side of the implant to space the members from the implant to permit cement to be positioned between the members and the implant. The positioner may also prevent the implant from rising out of the femoral canal beyond a predetermined position.

[0021] The positioner may include metal, ceramic, polymer, and/or other suitable biocompatible materials. For example, a polymer implant may include polyester, polyethylene, polyamides, polymethylmethacrylate, polyglycolic acid, polylactic acid, and/or other suitable nonresorbable and resorbable polymers. The positioner may include a polymer compatible with one or more polymers contained in a bone cement to be used with the positioner so that the positioner bonds to the cement and reduces stresses at the positioner/cement interface. For example, the positioner may include a polymethylmethacrylate polymer for use with cement including polymethylmethacrylate such that the positioner bonds to the cement.

[0022] FIGS. 1 through 3 depict an illustrative positioner 10 for controlling the position of a femoral component of a hip implant 12 within a femoral canal 14 of a femur 16. The femoral canal 14 includes a longitudinal axis 18 and a wall 20 surrounding the canal 14. The wall 20 has medial 22, lateral 24, anterior 26, and posterior 28 aspects. The femur 16 has a proximal portion 30 adjacent the opening 32 of the canal 14 and a distal portion 34 spaced downwardly from the proximal portion 30. The hip implant 12 includes a femoral component 36, a head 38, an acetabular shell 40, and an acetabular liner 42. The femoral component 36 is positioned within the canal 14 and supports the head 38. The acetabular shell 40 is positioned within the pelvis (not shown) and supports the acetabular liner 42. The head 38 articulates with the acetabular liner 42 to restore joint function. The femoral component 36

includes a stem 44 having a distal tip 46 positioned deep within the canal 14 and a proximal shoulder 48 positioned near the opening 32 of the canal 14. A neck 50 projects from the shoulder 48 to support the head 38. A distal stem positioner 47 helps centralize the distal tip 46 within the canal 14.

[0023] The illustrative femoral component 36 is embedded in cement 52 within the canal 14 and includes a polished and tapered exterior surface 54 permitting the femoral component 36 to move relative to the cement 52 after the cement has cured. Thus, the illustrative femoral component 36 may subside distally into the cement 52 under load to maintain intimate contact with the cement 52 even if the cured cement 52 deforms in use.

[0024] The positioner 10 includes a first member, or top 60, positionable over a portion of the femoral component 36 to prevent the femoral component 36 from rising out of the femoral canal beyond a predetermined position. In the illustrative embodiment, the top 60 is positioned over the shoulder 48 of the implant. However it is contemplated that the top 60 may be positioned over other portions of the femoral component 36 relative to the canal 14 axis 18 so that the femoral component 36 is prevented from rising from the canal 14 by abutment against the top 60. For example, the top 60 may be positioned over a projection anywhere along the stem 44. Alternatively, the positioner 10 may include a portion that fits within a recess in the stem 44.

[0025] The positioner 10 further includes a second member, or lateral leg 62, for anchoring the top 60 relative to the canal 14 and/or cement 52. In the illustrative embodiment, the lateral leg 62 extends at an angle from the top 60 and is embedded in the cement 52 to anchor the top 60 relative to the cement 52. However, the lateral leg 62 may also be anchored in bone, for example by driving it into the femur 16 adjacent the canal 14 and thus anchor the

top 60 relative to the canal 14. Scallops 63 in the lateral leg 62 create a positive engagement with the cement 52 and/or femur 16 to enhance the fixation of the lateral leg 62. [0026] The positioner 10 further includes anterior 64 and posterior 66 members, or legs, extending from the top 60 and/or lateral leg 62 to grip the femoral component 36. In the illustrative embodiment, the anterior 64 and posterior 66 legs are elastic and are biased inwardly to grip the femoral component 36. However, other means for gripping the implant are contemplated and fall within the scope of the present invention. The anterior 64 and posterior 66 members may be embedded in the cement 52 as shown to assist in anchoring the top 60.

[0027] The positioner 10 further includes a boss 70 projecting downwardly from the top 60 to engage a recess 72 in the shoulder of the femoral component 36 in radial force transmitting relationship. The boss 70 helps to maintain the positioner 10 in proper orientation relative to the femoral component 36. Furthermore, the radial spacing of the boss 70 and one or more of the legs 62, 64, 66 maintains a predetermined spacing between the femoral component 36 and canal 14 wall 20. In the illustrative embodiment, the boss 70 and lateral leg 62 form an "L"-shaped spacer with a top 60 positionable over and engageable with a portion of the femoral component 36 and a lateral leg 62 positionable adjacent the canal 14 wall 20 to space the femoral component 36 from the lateral aspect 24 of the canal 14 wall 20. Where present, the anterior 64 and posterior 66 legs may likewise provide a predetermined radial spacing from the anterior 26 and posterior 28 aspects of the canal 14 wall 20. In the illustrative embodiment, the engagement of the top 60 and femoral component 36 is shown as a male boss 70 on the positioner 10 and a female recess 72 on the femoral component 36. However, it is contemplated that these may be reversed so that a male feature on the femoral

component 36 engages a female feature on the positioner 10. Likewise, other engagement features providing for radial spacing are contemplated and fall within the scope of the present invention.

[0028] The lateral 62, anterior 64, and posterior 66 legs further include projections, or tabs 68, to space the members from the femoral component 36 and allow the cement 52 to be positioned between the legs 62, 64, 66 and the femoral component 36 so that the cement 52 makes direct contact with the femoral component 36. In addition, the tabs 68 may project a sufficient predetermined distance to substantially fill the space between the femoral component 36 and the canal 14 wall 20 and act to radially space the femoral component 36 from the canal 14 wall 20. The tabs 68 and boss 70 may be separately used or used in combination as shown.

[0029] In the illustrative embodiment, the positioner 10 is a unitary, "T"-shaped construct with legs projecting downwardly from the ends of the "T" and the boss 70 projecting downwardly from the intersection of the "T". The illustrative positioner 10 has a flat, rectangular cross-section throughout. However, other configurations and cross-sectional shapes are contemplated and fall within the scope of the present invention. In the illustrative embodiment, the positioner 10 is injection molded from an acrylic polymer. Such a positioner may be made from processes including machining from solid stock, injection molding, stamping and bending, and/or other suitable processes.

[0030] In use, the femur is prepared by creating an opening 32 into the femoral canal 14 and reaming the canal 14 to a suitable size to receive the femoral component 36. Liquid bone cement 52 is introduced into the canal 14 and the femoral component 36 is inserted into the cement 52. The positioner 10 is inserted into the cement 52 so that it becomes firmly

attached to the cement 52 upon hardening of the cement 52. Alternatively, the positioner may be attached to the femur 16 adjacent the canal 14, with or without cement, for example, by driving one or more of the legs 62, 64, 66 into the bone. The positioner 10 can be inserted simultaneously with or after the femoral component 36. If the positioner 10 is being used to radially position the femoral component 36, the positioner 10 is engaged with the femoral component 36, such as by inserting the boss 70 into the recess 72 and/or clipping one or more of the legs 62, 64, 66 around the femoral component 36. The femoral component 36 is then radially adjusted so that the positioner 10 engages the canal 14 wall 20 to space the femoral component a predetermined distance from the wall 20. For example, the femoral component 36 is pushed laterally until the lateral leg 62 is pressed against the lateral aspect 24 of the canal 14. Once the positioner 10 is firmly attached to the cement 52 and/or femur 16, it will prevent the femoral component 36 from rising up out of the canal 14 beyond a predetermined position as the femoral component 36 abuts the positioner 10. However, the positioner 10 permits the femoral component 36 to subside down into the canal 14. [0031] Although embodiments of implants and their use have been described and illustrated in detail, it is to be understood that the same is intended by way of illustration and example only and is not to be taken by way of limitation. Accordingly, variations in and modifications to the implants and their use will be apparent to those of ordinary skill in the art, and the following claims are intended to cover all such modifications and equivalents.